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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,929	12/02/2002	John J. Heine	1372.66.PRC	6456
21901	7590	12/27/2005	EXAMINER	
SMITH & HOPEN PA 15950 BAY VISTA DRIVE SUITE 220 CLEARWATER, FL 33760			LIN, JERRY	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/065,929	HEINE ET AL.	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicants' arguments, filed September 14, 2005, have been fully considered and they are deemed to be persuasive in-part. New grounds of rejection are made in light of the amendments made to the claims. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "higher" and "lower" in claim 1 is a relative term which renders the claim indefinite. The term "higher" and "lower" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicants have responded to this rejection by amending instant claim 1 to state that the values of higher and lower are within 0 and 1. However, it remains unclear what values within the range of 0 and 1 are higher and lower, i.e., at what value does the risk become sufficiently low to be lower. In addition, Applicants specifically define a

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value of higher as equivalent to 1 and a value of lower as equivalent to 0. By assigning higher to the value of 1, and lower to the value of 0, it is unclear if the applicants meant to only have a binary valuation system wherein there are only two values of risk, i.e., 1 or 0. For purposes of this examination, the Examiner will interpret that the risk probability value may be a value between 1 and 0.

This rejection is maintained and necessitated by amendment.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 9, 10, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (US 5,133,020) in view of Huo et al. (US 6,282,305).

Regarding claim 1, Giger et al. teach identifying a standard threshold of the computer algorithm for identifying false positive abnormalities (column 6, lines 33-column 9, line 10); and adjusting the threshold for identifying false positives based on the risk associated with a patient (column 12, line 58-column 13, line 7).

However, Giger et al. does not specifically teach calculating breast cancer risk.

Regarding claim 1 and claim 12, Huo et al. disclose a method which includes establishing a risk probability with a patient with factors such as age wherein the risk probability is between 0 and 1 (column 5, lines 55-63; column 6, line 25-40); applying a computer algorithm to find abnormalities in a patient's mammogram (column 9, lines 30-48).

Regarding claims 2 - 4, Huo et al. also discuss relative risk and absolute risk (column 3, lines 25-40) as well as include specific odds ratios in regard to breast cancer (column 3, line 66 - column 4, line 5).

Regarding claim 5, Huo et al. disclose determining parenchymal patterns (breast tissue density) (column 8, line 61-column 9, line 7; column 7, lines 18-37); integrating breast tissue density in the risk probability value (column 8, line 61-column 9, line 7; Figure 10).

Regarding claim 9, Huo et al. also disclose a data entry interface (Figure 13; column 29, lines 10-61); digitally acquiring the patient's mammogram (column 37, claim

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45; column 29, lines 10-61); applying the algorithm to the mammogram (column 37, claim 45; column 29, lines 10-61).

Regarding claim 10, Huo et al. disclose storing risk factors on electronic storage medium with digitally acquire mammogram (column 37, claim 45 – column 38, claim 48; column 29, lines 10-61).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. with Giger et al. to gain the benefit of using known risk analysis methods to improve the prognosis or diagnosis of breast cancer based on mammograms. Giger et al. indicates that the threshold may be adjusted for the risk assessment of a patient for better evaluation of a mammogram (column 12, line 58-column 13, line 7). Based on their recommendation, one of ordinary skill in the art would be motivated to search for a method of calculating breast cancer risk. Huo et al. provides methods of calculating breast cancer risk. One of ordinary skill in the art would be motivated to combine the references of Giger et al. and Huo et al. in order to carry out Giger et al.'s method as he indicates.

This rejection is necessitated by amendment.

Claims 6 -8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (US 5,133,020) in view of Huo et al. (US 6,282,305) in view of Wang (US 6,266,435).

Giger et al. and Huo et al. is applied as above.

Neither Giger et al. or Huo et al. teaches flagging mammograms or recommending a course of action.

Regarding claims 6 and 7, Wang discloses flagging (marking or annotating) positive or negative results of mammograms (column 8, lines 47-65).

Regarding claim 8, based on the results of the method, the physician recommends a course of action, which would include more invasive procedures for high probability of breast cancer or less invasive procedures for low probability of breast cancer (column 2, lines 51-55).

Regarding claim 11, Wang discloses presenting the results with computer aided enhancement (column 7, lines 37-56).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. and Giger et al. with Wang to gain the benefit of electronically annotating the mammogram images. Wang discloses that his method offers to advantage of offering a physician or technician additional information to aid in the interpretation of the mammogram image as well as to aid in determining the best course of action for a patient (Wang, column 4, lines 1-16). Huo et al. and Giger et al. both disclose methods of interpreting digital mammogram images to aid physicians. Thus, one of ordinary skill in the art would be motivated to combine the methods of Huo et al., Giger et al., and Wang to provide a complete set of tools to aid a physician in interpreting mammograms.

This rejection is necessitated by amendment.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

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PRIMARY EXAMINER

JL